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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|----------------------|---------------------------------|------------------|
| 09/937,678 | 09/28/2001 | Eric Goutay | PF 100 PCT US | 5103 |
| 25666 | 7590 05/07/2003 | | | |
| THE FIRM (| OF HUESCHEN AND | EXAMINER | | |
| 500 COLUMBIA PLAZA 350 EAST MICHIGAN AVENUE KALAMAZOO, MI 49007 | | | EVANS, CHARESSE L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 DATE MAILED: 05/07/2003 | þ |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | |
|---|---|---|--|--|--|
| · • • | 09/937,678 | GOUTAY ET AL. | | | |
| Office Action Summary | Examin r | Art Unit | | | |
| | Charesse L. Evans | 1615 | | | |
| The MAILING DATE of this communication | | | | | |
| Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REI THE MAILING DATE OF THIS COMMUNICATIO - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a - If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by sta - Any reply received by the Office later than three months after the may earned patent term adjustment. See 37 CFR 1.704(b). Status | N. 1.136(a). In no event, however, may a re reply within the statutory minimum of thirt od will apply and will expire SIX (6) MON tute, cause the application to become AB | eply be timely filed by (30) days will be considered timely. THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133). | | | |
| 1) Responsive to communication(s) filed on £ | <u> 6 February 2003</u> . | | | | |
| 2a)☐ This action is FINAL . 2b)⊠ | This action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4) Claim(s) 26-44 is/are pending in the applic | ation. | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | Claim(s) is/are allowed. | | | | |
| 6)⊠ Claim(s) <u>26-36 and 39-42</u> is/are rejected. | Claim(s) <u>26-36 and 39-42</u> is/are rejected. | | | | |
| 7) Claim(s) <u>37,38,43 and 44</u> is/are objected to | 7) Claim(s) <u>37,38,43 and 44</u> is/are objected to. | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner. | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a)⊠ All b)□ Some * c)□ None of: | | | | | |
| 1.☐ Certified copies of the priority docum | | | | | |
| 2. Certified copies of the priority docum | 2. Certified copies of the priority documents have been received in Application No | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | |
| Attachment(s) | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper Note | 5) Notice of I | Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-152) | | | |
| U.S. Patent and Trademark Office PTO-326 (Rev. 04-01) Office | Action Summary | Part of Paper No. 6 | | | |

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DETAILED ACTION

Priority

This application is a 371 of PCT/FR00/00803, filed March 3, 2000.

Action Summary

Acknowledgement is made of applicant's election, with traverse, of claims 26-44. Acknowledgement is made of the cancellation of claims 45-50.

Claims 26-44 are active in this action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the

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obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26-36 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derrieu et al (US 5,527,783). The claims are directed to a composition that has a fast-dissolving isotropic microporous expanded structure. [E] ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the productby-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re-Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Derrieu teaches a solid composition based on plants, comprised of an active principle, diluents, binders, coloring and flavors (column 4, lines 7-12). The diluents of preference include lactose and mannitol (column 4, lines 27-28). The binders include gums such as gum Arabic, alginates, pectins, gelatin, xanthane gum, dextrin and polyvinylpyrrolidone (column 4, lines 29-39). The additives used in the referenced invention are those normally used in the pharmaceutical and food industry and are compatible with the active principles present (column 4, lines 39-43).

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While the reference does not expressly teach applicant's claimed percent weights, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Regarding the disintegration time of less than 1 minute, in a composition claim, patentable weight is not given to the physical parameter or reason for including that component, as long as all of the necessary components are present. Furthermore, when a component is included in a composition, all of its properties and advantages are inherent to the composition. The presence of the component is all that is needed to render obvious applicant's claim.

One of ordinary skill in the art would be motivated to modify the teachings of Derrieu to include a broader spectrum of active agents within the composition with the expectation of being able to utilize the composition across multiple disciplines.

Claim Objections

Claims 37, 38, 43 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on Monday-Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THURMAN K. PAGE SUPERVISORY PATENT EXAMINER TECHNOLOGY PENTER 1600